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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,492	08/18/2000	Gary Van Nest	377882000800	7136

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MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

/

Office Action Summary	Application No.	Applicant(s)	
	09/642,492	VAN NEST ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13-23,25-33 and 37-52* is/are pending in the application.

4a) Of the above claim(s) *43-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,13-23,25-33 and 37-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In the response submitted June 14, 2004, applicant amended claim 1 and cancelled claims 11 and 53. Claims 1, 13-23, 25-33 and 37-52 are pending and claims 43-52 remain withdrawn from consideration due to a nonelected invention. Claims 1, 13-23, 25-33 and 37-42 are under consideration.

Specification

The specification is objected to for failing to adhere to the requirements of the sequence rules. Applicant must append SEQ ID Nos. to all mentions of specific amino acid sequences comprising four or more amino acids in the specification. Specific examples within the specification that do not comply with the sequence rules are found on page 7, line 9 for example. Applicant is required to append a SEQ ID NO. to any sequence applicable to the rule. See 37 CFR § 1.821 (a)-(d) and MPEP § 2422.

Appropriate correction is required.

Claim Objections

Claims 27 and 30 are objected to because of the following informalities: The claims recite four or more amino acids in a sequence that do not have sequence identifiers according to 37 CFR § 1.821 (a)-(d) and MPEP § 2422. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 13-23, 25-30, 32, 33 and 37-42 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for using an ISS molecule comprising SEQ ID NO: 1, does not reasonably provide enablement for IS sequences that are shorter or do not conform to the enabled motif. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In response to the rejection, applicant cites pages in the specification that discusses the ISS molecule and how it can be made and evaluated for immunomodulatory activity, as well as ISS-antigen complexes for use in the invention. Applicant also summarizes the teachings of Fearon et al.

Applicant states that the unconjugated ISS, "free ISS" and the ISS-cPLGA complexes of Fearon et al. both differ from the ISS-antigen complex of the instant invention and is not an appropriate standard of comparison.

Applicant's argument and a review of the reference and the instant claims have been fully considered, but are found unpersuasive. The instant claims are drawn to a method that requires two components: (i) a complex comprising an immunomodulatory polynucleotide (ISS) that has been complexed with an antigen. A Fearon et al. teaches an ISS complexed to another molecule, cPLGA. The instant claims additionally require a second component (ii) a second antigen. Fearon et al. do not teach an antigen, but the instant second antigen is not complexed to an ISS and Fearon et al. teach the activity of ISS molecules that are uncomplexed. Therefore, the free ISS and complexed ISS molecules of Fearon et al. are comparable to the instant ISS-complexes and antigens that are uncomplexed with ISS.

Applicant states that Fearon et al. clearly demonstrate that an ISS can have very different activities when presented alone or when in a complexed state. Applicant points to the activity of TCGTCGA in Figure 2 of Fearon et al. as an example.

In response, the different activities of uncomplexed and complexed ISS molecules, as exemplified by the TCGTCGA of Fearon et al. has been duly noted. Applicant has identified another unpredictable characteristic for the skilled artisan regarding the use of ISS molecules. The instant claims are drawn to ISS molecules of different lengths and sequences. However, there is no data presented in the specification that would indicate that any of the ISS molecules claimed (except for SEQ ID NO: 1), would be immunostimulatory when uncomplexed or complexed with another molecule. Although the claims require that the ISS molecules be immunostimulatory, see (i) of claim 1, there is no evidence provided in the disclosure that indicates that they are immunostimulatory. The claims require this characteristic, but invite the skilled artisan to prove the assertion stated in the claims.

With respect to the lack of immunostimulatory activity of complexed and uncomplexed ACGTTCG in Figure 2 of Fearon et al., applicant cites Figures 2 and 3 of Fearon et al. and argues that Fearon et al. also demonstrate many other CG-containing oligonucleotides of varying length and sequence that are immunostimulatory.

Applicant's arguments have been considered, but are found unpersuasive. Fearon et al. clearly show that just because an ISS molecule has two CpG motifs present (see the first paragraph of section 2.2), the determination of whether it possesses immunomodulatory effects cannot be determined without experimentation. In fact, the sequence ACGTTCG of Fearon et al. comprises two CpG motifs and is only one amino acid short of the second amino sequence listed

in claim 30. However, this sequence is demonstrated to be non-immunogenic when in a complexed and non-complexed form, see Figure 2 of Fearon et al. Therefore, whether the genus of ISS molecules encompassed by claims 1, 25-30 and 37 are immunogenic is unpredictable.

Applicant asserts that the presence of inoperative embodiments within the scope of a claim does not necessarily render the claim nonenabled. Applicant submits that the instant disclosure provides ample teaching for the skilled artisan to follow to test whether an oligonucleotide possesses immunostimulatory activity. Applicant cites *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), which states that the a considerable amount of routine experimentation is permissible, as long as the specification provides a reasonable amount of guidance with regard to how the experimentation should proceed.

In response, the Office is in concurrence with the decision cited by applicant. However, the instant claims encompass a broad genus of polynucleotide molecules that are required and characterized as being immunostimulatory, see claim 1. Upon reading the instant claims, the skilled artisan would naturally assume that the genus of ISS molecules encompassed by claim 1 and those specifically recited in claims 27 and 30 are immunostimulatory simply because the claims assert that they are. Therefore, when that same skilled artisan practices the method claimed and realizes that the goal of the method is not reached, the skilled artisan would not know the reason until each element, component and step of each of the instant claims were analyzed by experimentation. Therefore, the instant claims encompass a broad genus of IS polynucleotide sequences, but invite the skilled artisan to experiment and determine whether or not the IS sequences are immunostimulatory, as they are claimed to be. MPEP § 2164.08(b) states that:

Although, typically, inoperative embodiments are excluded by language in a claim (e.g., preamble), the scope of the claim may still not be enabled where undue experimentation is involved in determining those embodiments that are operable.

However, claims reading on significant numbers of inoperative embodiments would render claims nonenabled when the specification does not clearly identify the operative embodiments and undue experimentation is involved in determining those that are operative. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1577, 224 USPQ 409, 414 (Fed. Cir. 1984); *In re Cook*, 439 F.2d 730, 735, 169 USPQ 298, 302 (CCPA 1971).

The instant claims encompass a broad genus of "immunomodulatory" polynucleotide molecules, but the disclosure provides no data or requisite structural formulas that the polynucleotides must possess in order to be "immunomodulatory", as they are required to be. However, Fearon et al. provide data that clearly indicates that just because a polynucleotide formulation possesses CpG motifs, does not necessarily mean that the polynucleotide will be immunostimulatory. Applicant has not provided any data refuting the teachings of Fearon et al. Therefore, it is maintained that whether the genus of ISS polynucleotides claimed actually are immunostimulatory is unpredictable.

Applicant discusses the first paragraph of the discussion section and Figure 2 of Fearon et al. Applicant concludes that Fearon et al. is describing sequences that result in the optimal activity of the ISS and is directed to optimization of ISS activity rather than identifying sequences with some activity.

Applicant's discussion has been considered. While it is agreed that Fearon et al. do discuss an interest in optimal results, Fearon et al. also discover minimal ISS sequences required for the induction of IFN, see the abstract (emphasis added). Fearon et al. also discover crucial CpG motif positioning to induce an immune response, see Figure 2 and the second paragraph of the discussion section. Therefore, contrary to applicant's assertion, Fearon et al. are concerned with identifying sequences with some activity as well as optimizing that activity.

In conclusion, the Office has met a prima facie case of non-enablement since there is sufficient evidence in the post-filing date ISS art of Fearon et al. that whether ISS molecules are immunostimulatory is unpredictable. Therefore, it is maintained that the instant claims would require an undue quantity of experimentation to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 13, 14, 17, 20-23, 25-33, 37 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (WO 98/55495, "Schwartz") **or** Carson et al. (WO 98/16247, "Carson"), as further evidenced by Horner et al. (Cellular Immunology. November, 1998; 190: 77-82) or Chu et al. (Journal of Experimental Medicine. 1997; 186 (10): 1623-1631) for reasons of record.

Applicant argues that nothing in Schwartz or Carson teach or suggest that the modulation of the immune response to a free antigen would be greater if the free antigen was administered with an ISS-antigen complex, instead of a free ISS. Applicant asserts that the ordinary artisan would have no expectation of success for producing this effect from the teachings of Carson or Schwartz.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the immune response would be greater against a second antigen when administered with an ISS-antigen complex that co-administration with a free ISS) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicant argues that the ordinary artisan would not be motivated to administer a second antigen from the teachings of Schwartz or Carson. Applicant disagrees with the citation from the previous Office action of Page 12, lines 9-15. Applicant recites the lines and interprets combinations of components from the passage. Applicant concludes that Schwartz does not specifically suggest that ISS is administered with more than one antigen. Applicant also cites page 12, lines 29-31 and page 14, lines 8-14 as further evidence that Schwartz only intends one antigen to be administered with the ISS molecule.

Applicant's arguments and a careful review of the passages cited have been fully reviewed, but are found unpersuasive. In the previous Office action, the Office cited the exact same passage on page 12, lines 9-15 that applicant discusses above because the passage very

clearly suggests that more than one antigen can be administered with the ISS molecules from the teachings of Schwartz. The passage is herewith recited and explained again. On page 12, lines 9-10, the passage explicitly states: "ISS can be administered in conjunction with one or more members of the group of immunostimulatory molecules comprising antigens..." (emphasis added). Applicant appears to interpret this passage as meaning that the ISS is administered with one single type of immunostimulatory molecule or another single immunostimulatory molecule. However, the immunostimulatory molecules (plural) of Schwartz are defined as antigens (plural), see the exact recitation above. Schwartz explicitly states that antigens (plural) are combined with ISS. Schwartz even linguistically emphasizes this plurality with the phrase "one or more". Therefore, it is maintained that Schwartz explicitly suggests combining more than one antigen with the ISS molecule.

Regarding the passage on page 12, lines 29-31, applicant appears to be arguing that this passage is further evidence that Schwartz only suggests one antigen in conjunction with an ISS molecule. However, the plurality of antigens that can be combined with the ISS molecule is discussed in the previous paragraph (containing the sentence that is recited and dissected above). In this passage (page 12, lines 29-31), Schwartz is discussing other aspects of the invention. Specifically, the reference is teaching how the ISS and other multiple components administered with it are encompassed within the invention (emphasis added). The instant claims are drawn to a method with two components: (i) an ISS-antigen complex and (ii) and un-complexed second antigen. On page 12, lines 29-31, Schwartz states that "[t]he ISS and the antigen...can be administered together in the form of a conjugate" (this teaching embraces (i) of the instant claims) "or co-administered in an admixture sufficiently close in time so as to modulate an

immune response" (since the instant un-complexed second antigen is co-administered with the ISS complex, this phrase embraces (ii) of the instant claims). Schwartz also discusses these same concepts again on page 14, lines 8-14.

Applicant argues that neither Horner nor Chu teach or suggest the co-administration of an ISS-first antigen complex and a second antigen. However, if either of the references taught these concepts, the references would have been required to be cited under the anticipatory statute, 35 U.S.C. § 102. Both references are cited because both teach that a Th1 response is induced against an antigen that is co-administered with an ISS molecule.

In the last paragraph on page 15 of the response, applicant argues an inadvertent phrasing presented in the previous Office action. In the Office action mailed June 2, 2003, it is clear that Carson teaches an immunomodulatory composition comprising an ISS conjugated to an antigen.

In the first paragraph on page 16 of the response, applicant reasons that if the cited references suggest the administration of a second antigen with an ISS-first antigen complex, the knowledge in the art would suggest to the skilled artisan that co-administration of an ISS-antigen complex with another un-complexed antigen would result in an immune response similar to that of an admixture of an ISS and the un-complexed antigen.

The claims are drawn to modulating an immune response to a second antigen by co-administering an ISS-antigen complex and a second antigen. The prior art cited clearly teaches that ISS-antigen complexes induce an immune response and that ISS/antigen mixtures induce an immune response. The immune response induced by an ISS/antigen mixture is an immuno-modulation against the unconjugated antigen, which is all that us required by the claims. Therefore, it is established by the prior art that the ordinary artisan would have a reasonable

expectation of modulating an immune response to an unconjugated, second antigen absent evidence to the contrary.

Applicant argues that the instant method would result in a very different result from that which would flow from the teachings of Schwartz or Carson. Applicant points to the results in the declaration provided by Dr. Van Nest., which shows that a greater immune response is induced against a second antigen when co-administered with an ISS-antigen conjugate than when an antigen and the ISS is administered as a mixture.

Applicant's arguments have been fully considered, but are found unpersuasive because the claims do not recite the imitations applicant is arguing. The claims are drawn to modulating an immune response to a second, unconjugated antigen when co-administered with an ISS-antigen complex. The cited prior art clearly indicates that ISS/antigen mixtures induce an immune response to the antigen and that ISS-antigen complexes induce an immune response to the antigen. Therefore, the prior art clearly indicates that an immune response would be induced, i.e. modulated, against an un-complexed antigen when it is co-administered with an ISS molecule, which is all that is required by the instant claims.

Claims 15 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., as further evidenced by Horner et al. or Chu et al., as applied to claims 1, 11, 13, 14, 17, 20-23, 25-33, 37 and 40-42 above, and further in view of Lee et al. (Ann Med. 1998; 30: 460-468) for reasons of record.

Applicant argues that Lee does not supply what is missing from the primary references. Applicant further submits that there is no suggestion to modify the references to arrive at the claimed invention.

Applicant's arguments have been fully considered, but are found unpersuasive because administering a second antigen with an ISS-antigen conjugate would have been obvious from the teachings of Schwartz or Carson, respectively, as evidenced by Horner et al. or Chu et al. Each reference individually teaches inducing a Th-1 response against an antigen present in a mixture with an ISS molecule or in an ISS-antigen complex. Therefore, Lee is only required to teach a limitation that is not taught by the primary references.

Lee et al. teach that the influenza nucleocapsid protein is the least effected by antibody-induced antigenic drift and studies using DNA encoding this protein have demonstrated protection, see "infectious diseases" on page 465. One of ordinary skill in the art would have been motivated to incorporate a protein into a treatment composition that has already demonstrated protective properties in other studies. Furthermore, one of ordinary skill in the art would have had a reasonable expectation in producing the claimed invention because Schwartz or Carson teach compositions and methods comprising ISS and proteins that modulate the immune response and Lee et al. also teach subsequent Th1 responses upon administration of ISS with DNA encoded antigens, see "mechanism of action..." on pages 463-464. Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results.

Claims 16 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., as further evidenced by Horner et al. or Chu et al., as applied to claims 1, 11, 13, 14, 17, 20-23, 25-33, 37 and 40-42 above, and further in view of Durali et al. (J of Virol. 1998; 72(5): 3547-3553) for reasons of record.

Applicant also argues that this reference does not overcome the deficiencies of Carson or Schwartz or provide motivation to arrive at the claimed invention.

Applicant's arguments have been fully considered, but are found unpersuasive because administering a second antigen with an ISS-antigen conjugate would have been obvious from the teachings of Schwartz or Carson, as further evidenced by Horner et al. or Chu et al. Each reference individually teaches inducing a Th-1 response against an antigen present in a mixture with an ISS molecule or in an ISS-antigen complex. Therefore, Durali et al. is only required to teach a limitation that is not taught by the primary references.

Durali et al. teach that the gag protein is capable of cross-reactivity in different patients infected with different clades of HIV, see the abstract. Since high variability in HIV is a major obstacle in selecting an antigen for a vaccine candidate and Durali et al. have been able to identify a conserved protein, one of ordinary skill in the art would be motivated to incorporate this protein into a composition to induce an immune response against the antigen. Furthermore, the skilled artisan would have a reasonable expectation in producing the claimed invention because Schwartz et al. or Carson et al. teach that the protein portion of the composition and method could be a wide variety of proteins from viruses.

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. or Carson et al., as further evidenced by Horner et al. or Chu et al., as applied to claims 1, 11, 13, 14, 17, 20-23, 25-33, 37 and 40-42 above, and further in view of Anderson (US Patent 4,673,574) for reasons of record.

Applicant argues that none of the references alone or in combination teach potentiating an immune response against a second antigen that is co-administered with an ISS-antigen complex.

Applicant's arguments have been fully considered, but are found unpersuasive because administering a second antigen with an ISS-antigen conjugate would have been prima facie obvious from the teachings of Schwartz or Carson, as further evidenced by Horner et al. or Chu et al. Each reference individually teaches inducing a Th-1 response against an antigen present in a mixture with an ISS molecule or with an ISS-antigen complex. Therefore, is Anderson is only required to teach a limitation that is not taught by the primary references.

In the instant case, one of ordinary skill in the art at the time the invention was made would have been motivated to use the diphtheria components taught by Anderson in the method and composition taught by taught by Schwartz et al. or Carson et al. when administering the composition to children or immunocompromised individuals because the diphtheria toxins aid in eliciting a protective immune response, have no toxicity, and can be administered safely to children, see column 5, lines 10-19 and column 14, table 7. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation in producing the claimed invention because Schwartz et al. or Carson et al. teach that the ISS/antigen composition can be combined with any known vaccine component and the diphtheria toxins taught by Anderson are well known.

Conclusion

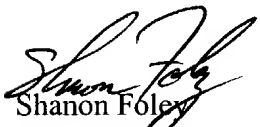
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Patent Examiner, 1648